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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,715	03/03/2004	Gregory M. Glenn	056707-5001-01	4303

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
KIM, YUNSOO	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,715	GLENN ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *106-161* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *106-161* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 71-105 have been canceled.
Claims 106-161 have been added.
Claims 106-161 are pending.

2. Sequence compliance: The instant application appears to be in sequence compliance for patent applications containing amino acid sequence disclosures.

3. Applicants' IDS filed on 11/8/05/04 is acknowledged

4. Upon Applicant's cancellation of the previously pending claims, the rejections (sections 6-10) set forth in the office action mailed 7/8/05 have been withdrawn.

5. The following new grounds of rejections are necessitated by Applicants' addition of new claims filed on 11/8/05.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 142-161 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection for the following reasons:

The specification as filed does not provide a written description or set forth the metes and bounds of the phrases " wherein said area of the skin comprises a draining lymph node filed" and " to the same draining lymph node field" in claim 142. The specification does not provide any guidance or direction for the above-mentioned phrases as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now

change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant's provision of written support on p. 10, lines 12-15 does not provide the written support for applying the formulation to the same draining lymph node.

Applicant is required to cancel the new matter in the response to this Office Action.

8. Claims 142-161 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

The specification does not reasonably provide enablement for a method of inducing an immune response comprising applying a formulation to more than one application site and site overlying more than one draining lymph node.

The antigenic stimulation at an application site results the lymph collected is filtered through a set of defined lymph nodes of the local area. Distal and multiple applications of antigens to cervical and abdomen areas would not result one draining lymph node (Kuby, 2000, Immunology, 4th ed. p. 47-53).

Thus, Applicant has not provided any guidance to enable one skill in the art to use claimed invention in manner reasonably correlated with the scope of enablement. In view or the quantity of experimentation necessary, the limited working example, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 106, 107, 109, 110, 114-121, 124, 125, 127, 128 and 132-139 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/17211(IDS reference).

The '211 publication teaches a transdermal (simultaneous, separate, or sequential, p. 8, lines 34-36) applications of the immunogenic composition comprising bacterial or viral antigen, genetically modified bARE or LT as adjuvants and pharmaceutically acceptable carrier (Abstract, p. 2, lines 12-25, p. 8, lines 8-38, p. 9, lines 14-20, p.12, lines 8-15).

Claims 116 and 134 are included in this rejection as the reference teaches polypeptide influenza antigen (i.e. Hemaglutinin A, p. 8, lines 20-23, p. 9, lines 2-24).

As the pretreatment of skin by chemical or hydration means (i.e. cleaning the skin with alcohol before application of medication) is well known procedure, thus, reference teachings anticipate the claimed invention.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 106 - 108, 113, 122-126, 131, 140 and 141 are rejected under 35 U.S.C. 103 as being unpatentable over WO 95/17211(IDS reference), in view of U.S. Pat. No.4, 810,499 (IDS reference).

The teachings of the '211 publication have been discussed, supra.

The '211 publication does not teach a patch in transdermal drug delivery system.

However, the '499 patent teaches the use of patch in transdermal delivery for rate controlled substance delivery, eliminating "first pass" inactivation by the liver and irregular gastric absorption in oral delivery (col. 1, lines 20-35, col. 2, lines 50-55).

The '499 patent further teaches penetration enhancement by hydration of stratum corneum (i.e outermost layer) to accelerate the drug delivery (col. 3, lines 32-45).

Therefore, one of the ordinary skill in the art would have been motivated to combine the transdermal patch taught by the '499 patent in the transdermal immunogenic composition comprising antigen, adjuvant and pharmaceutically acceptable carrier taught by the '211 publication because the patch taught by the '499 patent improves delivery (i.e. rate controlled), eliminates ineffective absorption by oral delivery.

From the teachings of references, one of the ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by references, especially in the absence of evidence to the contrary.

13. Claims 106, 111, 112, 124, 129 and 139 are rejected under 35 U.S.C. 103 as being unpatentable over WO 95/17211 (IDS reference), in view of U.S. Pat. No.5,814,599 (IDS reference).

The teachings of the '211 publication have been discussed, supra.

The '211 publication does not teach a device to pretreat the skin.

However, the '599 patent teaches the use of low frequency ultrasound to enhances transdermal transport of proteins to deliver therapeutic doses of protein across the skin (abstract, col. 1, lines 32-55).

Therefore, one of the ordinary skill in the art would have been motivated to combine the ultrasound in transdermal delivery taught by the '599 patent in the transdermal immunogenic composition comprising antigen, adjuvant and pharmaceutically acceptable carrier taught by the '211 publication because the ultrasound taught by the '599 patent enhances the transport of the drug and deliver therapeutic doses of protein across the skin

From the teachings of references, one of the ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by references, especially in the absence of evidence to the contrary.

14. No claims are allowable.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic
Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
January 12, 2006

Patrick, J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600